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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,666	02/09/2004	Ramez Emile Necola Shehada	064693-0092	1472

7590 08/14/2006

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EXAMINER	
HILL, LAURA C	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/775,666			

EXAMINER

ART UNIT	PAPER
	20060807

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Office Action Summary	Application No.	Applicant(s)	
	10/775,666	NECOLA SHEHADA ET AL.	
	Examiner	Art Unit	
	Laura C. Hill	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *44-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/26/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 6-7, filed 3 August 2006, with respect to the rejection(s) of claim(s) 44-67 under Lange (US 6,751,499) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Skrabal (US 5,097,834), Goodman et al. (US 4,938,218), Koehn (US 3,030,953), Santomieri (US 3,515,137), Beck (US 3,537,451), and Lange (US 6,751,499) as discussed below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 44-49, 51, 56-60 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange (US 6,751,499; herein 'Lange') in view of Skrabal (US 5,097,834; herein 'Skrabal').

Based upon the earlier effective U.S. filing date of the Lange reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application

and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Lange discloses a physiological monitoring system 100 comprising: components for measuring blood pressure, pulse, temperature, respiration and pain level (column 9, lines 25-28) that contact the skin surface (column 10, lines 14-17); a set of electrodes 12 on a sensor array/first, second and third sensing systems 13 (figures 4-5) having a color-coded strip which processes a pain signal using analog circuitry and presents the pain result as a specific color scale or gray scale intensity on a color display (column 9, lines 33-49) in a discrete reading format based on four levels of pain (column 9, lines 40-46), and further the system detects electric potential changes/spectral energy (column 10, lines 30-36). Lange further discloses an IV fluid container/drain placed within the body cavity and closed-loop analgesia system 140 that applies fluid into the body in combination with the physiological monitoring system (column 26, lines 33-45). Lange *does not expressly disclose* a drain implanted in the body but rather on top of the skin tissue. **Skrabal** discloses a surgical drain 5 for sensing a physiological property of tissue and draining fluid from a body (column 9, lines 13-17 and lines 23-25, column 6, lines 44-55) comprising: (a) an elongate conduit/catheter 2 configured to be inserted into the tissue (column 9, lines 10-12, column 11, lines 59-63) to drain fluid from the patient's body wherein the drain portion has openings 9 spaced along the length of the

wall (column 2, lines 34-40, column 9, lines 21-22, column 13, lines 36-37, figures 1 and 7g); and negative pressure sensor/first sensing system 18 located in the tubes 7, 7' of implanted catheter 2 (column 10, lines 41-45) that senses tissue glucose/ perfusion physiological property and compares these values with blood glucose values obtained simultaneously (column 21, lines 27-31). Skrabal further discloses pump 16 that delivers energy to the tissue (column 9, lines 40-51), a display 73 configured to depict data corresponding to the physiological property sensed by the first sensing system (column 18, lines 52-68), and a calibrating unit/processing system 20 (column 9, lines 59-64) and computer of evaluation unit 11 (column 9, lines 40-43). One would be motivated to modify the location of the sensing system of Lange with the sensing and drainage system of Skrabal for improved monitoring of any variety of physiological conditions inside the body since the references disclose systems with processing and display systems for communicating data collected from the body. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the system and thus providing a surgical drain in combination with a multiple physiological condition sensing system.

Regarding claims 52-55, 61 and 64-67 Lange discloses fiber optic connections and transducers that convert electrical signals from electrodes/sensing elements to light signals (column 11, lines 62-column 12, line 4) and are thus affixed and embedded within the conduit (figure 22).

3. Claims 50 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange (US 6,751,499; herein 'Lange') in view of Skrabal (US 5,097,834; herein

'Skrabal') as applied to claims 49 and 56, and further in view of Koehn (US 3,030,953), Santomieri (US 3,515,137) and Beck (US 3,537,451). Skrabal/Lange *do not expressly disclose* the sensing elements are embedded within a material that is optically transparent. It is well known to use transparent polyvinylchloride, polyethylene, polytetrafluoroethylene (also known as Teflon®), and polyurethane materials for catheters as taught by Harautuneian, Koehn, Santomieri and Beck. One would be motivated to modify the catheter material of Skrabal with the optically transparent catheter materials of Harautuneian, Koehn, Santomieri and Beck to provide a means to visually inspect the sensing elements through the conduit during use. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter material, thus providing an optically transparent material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill
Examiner
Art Unit 3761

LCH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER